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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,747	06/13/2006	Jasmina Dokic-Gallagher	D0886-00158	1138

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DUANE MORRIS LLP - Philadelphia  
IP DEPARTMENT  
30 SOUTH 17TH STREET  
PHILADELPHIA, PA 19103-4196

EXAMINER
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SULLIVAN, DANIELLE D

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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08/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,747	<b>Applicant(s)</b> DOKIC-GALLAGHER, JASMINA	
	<b>Examiner</b> DANIELLE SULLIVAN	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 29-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-53 is/are rejected.
- 7) ☒ Claim(s) 34 and 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/08/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-28 have been canceled in the amendment filed 6/08/2009. New claims 29-53 were added.

#### ***Information Disclosure Statement***

The information disclosure statement filed 6/08/2009 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Claim Objections***

Claim 34 is objected to because of the following informalities: "cyclomethlcone" should be spelled "cyclomethicone".

Claim 37 is objected to because of the following informalities: "aminimides" should be spelled "aminoamides". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 29-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 recites "an active ingredient selected from a bioadhesive polymer and pharmaceutically acceptable salts thereof in lice killing concentrations" which does not find support in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites "lice killing concentrations" which is indefinite. The specification does not provide antecedent basis for this term. Hence, the metes and bounds of the term cannot be deciphered.

Regarding claim 39, the phrase "e.g. lecithin..." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 45-52 recites the limitation "the carbomer" in reference to the bioadhesive polymer in claim 29. There is insufficient antecedent basis for this limitation in the claim.

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Claim 53 provides for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

### ***Claim Rejections - 35 USC § 101***

Claim 53 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 31, 33-35 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Cobb et al. (4,906,459).

Cobb et al. disclose a hair tonic composition comprising 0.95% cyclomethicone, 40% ethanol, 0.108% Carbomer 940, 0.10% triethanolamine (surfactant) and water to

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q.s. (Example III). Cyclomethicone is added to the ethanol, then the Carbomer 940 is mixed with water and added to the silicon/ethanol mixture (column 13, lines 20-32).

Claims 29-33, 35, 38, 47, 48 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Uhlmann et al. (5,520,905).

Uhlmann et al. disclose a composition comprising 1% phenyltrimethicone (silicone), 1% Carbomer (Carbopol 981), 3% butylene glycol (surfactant) and 5% ethanol (Example 2).

Claims 29-35, 38, 45-48, 51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Sine et al. (6,183,766).

Sine et al. discloses a compositions comprising 55% ethanol, 3% isopropanol, 0.25% carbomer, 0.58% Quadrol Polyol (surfactant), 8% cyclomethicone (Example III).

Claims 29-33, 35, 38, 47, 49, 51 and 53 are rejected under 35 U.S.C. 102(a) as being anticipated by Kawa et al. (2004/0044078).

Kawa et al. discloses a composition comprising 10% ethanol, 0.5% Carbopol, 3% dimethicone, glyceride surfactants and water to q.s. (Example 22).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 37, 39-44, 50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sine et al. (6,183,766).

### **Applicant's Invention**

Applicant claims a pediculicidal composition comprising an active ingredient selected a bioadhesive polymer and pharmaceutically acceptable salts thereof; and a physiologically acceptable carrier, wherein the carrier is a combination of an alcohol and a silicone based compound, where the alcohol is selected from isopropanol, ethanol and industrial methylated spirit. Claim 36 further adds a surfactant selected from N-acyl sarcosiates. Claim 37 further adds a surfactant selected from quaternary ammonium compounds. Claim 39 further comprises a triglyceride. Claim 40 specifies the pH of the composition is 4.5 to 8. Claims 41 and 42 further limit the bioadhesive polymer to comprising one or more co-monomers, preferably C10-C30 alkyl acrylates. Claims 43 and 44 specify the composition further comprises at least one additional component having ovicidal activity, preferably selected from terpenes, d-phenothrin, malathion, carbaryl, tea tree oil and neem oil. Claim 50 specifies the composition comprises 0.25-1% carbomer, up to 10% silicone and 10-30% isopropanol. Claim 52 specifies the composition comprises one carbomer, at least one surfactant, isopropanol and a component that delivers ovicidal activity.

### **Determination of the scope and the content of the prior art**

**(MPEP 2141.01)**

Sine et al. teach the formulation as disclosed in above 102(b) rejection. Sine et al. teach skin sanitizing compositions which kill microorganisms on skin surfaces without need of water and towels (column 1, lines 15-29). The compositions comprise 40-99% alcohol, preferably ethanol (column 2, lines 50-57). Lipophilic moisturizing agents are included from 0.1-20% of the formulation (column 2, lines 59-63). Preferably the moisturizing agents are selected from hydrocarbon oils, silicone oils and triglycerides (column 3, lines 32-65). Carbomers are selected from Carbopol, Stabylen and Pemulen (a C10-C30 alkyl acrylate) (column 11, lines 4-23). Antimicrobial agents may be present at concentrations from 0.05-1% and are selected from tea tree oil and benzalkonium chloride (quaternary ammonium surfactant) (column 12, lines 5-16, 22 and 55). Emulsifying surfactants selected from sodium stearyl sarcosinate may be used (column 14, line 21). Skin care actives may be added including insect repellants selected from synthetic pyretherins (column 15, lines 1-4). When zinc salts are added in the formulation is adjusted to less than 7 to keep the solution clear (column 10, lines 31-40).

**Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

Sine et al. do not give examples which disclose formulations comprising surfactants selected from N-acyl sarcosiates quaternary ammonium compounds or triglyceride. However, their incorporation into the formulations is taught.



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Sine et al. do not specify the pH of the composition is 4.5 to 8. However, adjusting the formulation to a pH under 7 is disclosed. Sine et al. teach that C10-C30 alkyl acrylates may be substituted as carbomers. The addition of a component having ovicidal activity is not disclosed, However, Sine et al. teach that antimicrobial agents may be present at concentrations from 0.05-1% and are selected from tea tree oil, and that insect repellants selected from synthetic pyretherins, d-phenothrin, may be added. Sine et al. do not disclose a specific composition comprises 0.25-1% carbomer, up to 10% silicone and 10-30% isopropanol. However, Sine et al. teach the compositions comprise about 40% alcohol and the examples disclose only 3% isopropanol.

#### **Finding of prima facie obviousness**

##### **Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Sine et al. to adjust the pH to 4.5 to 8 and the amount of isopropanol to 10-30% the formulation. One would have been motivated to manipulate ranges during routine experimentation to discover the optimum or workable range since the Sine et al. teach adjusting pH to under 7 and formulations comprising 3% isopropanol. Sine et al. teach adjusting the total alcohol to 40-99%. Therefore, one would have been motivated to use the appropriate amount of isopropanol relative to the ethanol in order to obtain this range.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE SULLIVAN whose telephone number is (571)270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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